In the United States Court of Federal Claims

No. 18-1303V
(Filed Under Seal: September 20, 2023)*
(Reissued: October 6, 2023)

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TARA DENNINGTON,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

Michael P. Milmoe, argued the motion for review, *Leah VaSahnja Durant*, counsel of record, Law Offices of Leah V. Durant, PLLC, of Washington, D.C., for Petitioner.

Tyler King, Trial Attorney, Torts Branch, Civil Division, U.S. Department of Justice, of Washington, D.C., for Respondent.

OPINION AND ORDER

SOMERS, Judge.

Before the Court is a motion for review of the Chief Special Master's decision denying compensation under the National Vaccine Injury Compensation Program, filed by Petitioner, Tara Dennington ("Petitioner"). *See* ECF Nos. 61, 62. The Secretary of Health and Human Services ("Respondent") filed a response to Petitioner's motion, *see* ECF No. 64 ("Response"), and the Court held oral argument on July 27, 2023.

In her motion for review, Petitioner seeks compensation pursuant to the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. §§ 300aa–10 to 34, contending that a tetanus, diphtheria, and acellular pertussis ("Tdap") vaccine caused her to develop Guillain-Barré syndrome ("GBS"). The Chief Special Master denied Petitioner's claim,

* On September 20, 2023, the Court issued this opinion and order under seal in accordance with Rule 18(b) of the Vaccine Rules (Appendix B) of the U.S. Court of Federal Claims. The Court provided the parties 14 days to proposed redactions. The parties did not propose any redactions, and, accordingly, the Court reissues this opinion and order in its original form.

concluding that: (1) Petitioner did not preponderantly establish that the Tdap vaccine she received could cause GBS, or (2) that it did so in a medically acceptable timeframe. Petitioner now seeks review of that decision. For the reasons provided below, the Court finds that Petitioner has not met the high burden imposed under the Vaccine Act to set aside a special master's decision and, therefore, denies Petitioner's motion for review.

BACKGROUND

A. Factual History

Petitioner has suffered from bouts of GBS, both as a child and as an adult. She alleges that she incurred the bout of GBS at issue here from a Tdap vaccine she received on August 30, 2015. The Chief Special Master's Entitlement Decision, *see Dennington v. Sec'y of Health & Hum. Servs.* ("Entitlement Decision"), No. 18-1303V, 2023 WL 2965239 (Fed. Cl. Apr. 17, 2023), detailed the facts, medical records, expert reports, and other evidence relevant to this case comprehensively, and, as a result, the Court will only provide a summary of the relevant events and evidence.

1. Previous GBS Diagnosis and Medical History

Prior to the vaccine at issue in this case, Petitioner had a medical history of abdominal pain, allergic rhinitis, gastroesophageal reflux disease, asthma, obsessive-compulsive disorder, anxiety, and irritable bowel syndrome. *Id.* at *1. On August 21, 2005, ten years prior to receiving the vaccination at issue here, Petitioner visited South Hermann emergency room and Texas Children's Hospital ("TCH") in Houston, Texas, complaining of bilateral facial paralysis, weakness, ataxia, and unsteadiness/dizziness with lightheadedness. *Id.* As a result, Petitioner was hospitalized. *Id.* While hospitalized, providers performed a head CT scan, lumbar puncture, and an MRI of Petitioner's spine, all of which came back normal, "with no evidence of demyelination." *Id.*

On August 24, 2005, Petitioner was diagnosed with GBS with bulbar involvement and treated with intravenous immunoglobulin ("IVIG").[1] *Id.* at *2. The hospital then transferred her from the intensive care unit to the progressive care unit, where she underwent occupational and physical therapy. *Id.*; ECF No. 13-1 at 25. On August 26, 2005, Petitioner received a rehabilitation evaluation at TCH. Entitlement Decision at *2. While the evaluation did not note any cognitive impairment or gagging with oral intake, it did note that Petitioner had "impaired oral motor function due to facial weakness" and "difficulty with some activities of daily living ('ADLs') due to ataxia." *Id.*; ECF No. 13-1 at 27. Petitioner continued rehabilitation, including speech, physical, and occupational therapy three times per week. Entitlement Decision at *2; ECF No. 13-1 at 27–28, 37. However, in her follow-up appointments at TCH, Petitioner continued to complain of persistent fatigue and facial weakness, "although her overall motor function had somewhat improved." Entitlement Decision at *2. Petitioner continued her rehabilitation therapy until she was discharged in April of 2006. *Id.*

[1] IVIG is a blood product used to treat patients with antibody deficiencies, including neurological disorders. *See* Jolles, Sewell & Misbah, *Clinical Uses of Intravenous Immunoglobulin*, NCBI (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1809480/ (last visited Aug. 8, 2023).

Three and a half years later, on September 11, 2009, Petitioner underwent another neurology consultation at the Houston Neurological Institute. Based on that consultation, Dr. Kathleen Eberle, M.D. concurred that "Petitioner's presentation was suggestive of the 'Miller Fisher variant of [GBS] and/or Bickerstaff's brainstem encephalitis.'" *Id.* (quoting ECF No. 7-10 at 1) (alterations in original). On January 7, 2010, Petitioner underwent an electromyogram that showed "evidence of a 'chronic sensorimotor neuropathy, predominantly demyelinating.'" *Id.* (quoting ECF No. 7-10 at 5). Several days later, Dr. Eberle wrote a letter that stated that Petitioner had been diagnosed with a variant of GBS in 2005, had "never achieved full recovery," had "some residual weakness and incoordination in the limbs," tended "to fatigue quickly," and continued "to have weakness in the muscles of her face and . . . abnormal movements/spasms in the face related to aberrant nerve regeneration." *Id.*; ECF No. 17-1 at 1.

2. 2015 Vaccination and GBS Treatment

Six years later, on August 30, 2015, Petitioner, then 25 years old, went to the emergency room at the Kingwood Medical Center ("Kingwood") in Kingwood, Texas for a rash and abscess after scraping her foot on an "old rusty pole." Entitlement Decision at *3. Petitioner received a Tdap vaccination. *Id.* Two days later, on September 1, 2015, Petitioner returned to Kingwood, reporting numbness and tingling that was worse in her lower extremities. *Id*. She also complained that her "foot just kinda fe[lt] asleep." *Id.* However, a physical examination did not show any abnormalities. *Id.* Petitioner's mother insisted that Petitioner needed to see a neurologist, and the two of them left Kingwood and went to TCH, where Petitioner complained of numbness on the left side of her face, leg, and toes. *Id.* Petitioner also reported that she had experienced a two-day fever, as well as nausea earlier that day. *Id.* Petitioner's mother indicated that Petitioner's symptoms were similar to those she experienced ten years earlier at the onset of her previous GBS episode in 2005. *Id.* When examined, Petitioner exhibited a normal respiratory exam, presented no signs of headaches or neck rigidity, and showed "full bilateral upper and lower extremity strength against resistance in all flexors and extensors . . . ." *Id.* She did, however, exhibit "decreased sensation in her left upper and lower extremities and left face." *Id.*

Later that same day, Plaintiff was transferred and admitted to Houston Methodist Hospital, where neurologist Robert Smith, M.D., evaluated Petitioner for possible GBS. *Id.* Upon a motor examination, Petitioner presented full strength in the right upper and lower extremities, but reduced strength in the left upper and lower extremities, as well as mild right facial weakness. *Id.* "The differential diagnosis," he stated, "included acute disseminated encephalomyelitis and GBS, along with possible nonorganic cause of weakness." *Id.* (internal quotations and citations omitted). The next day, on September 2, 2015, Petitioner underwent both a lumbar puncture and a brain MRI that produced normal results. *Id.* However, Petitioner still showed evidence of decreased reflexes, and her electromyography/nerve connection studies ("EMG/NCS") test showed decreased F-waves. *Id.*

Petitioner's neurological evaluation also noted that Petitioner "had 4+/5 strength in the left upper and lower extremities with normal strength on the right and a decreased 1+/4 reflex at the left knee, a normal 2+/4 reflex at the right knee, and absent reflexes at the ankles bilaterally."

Id. The evaluation further indicated that Petitioner "had mild objective weakness and subjective numbness on the left side, and, because of her history of a previous episode of the Miller-Fisher variant of GBS. . . [and] concern about a recurrence . . . [,] she was given five doses of IVIG." *Id.*

3. Treatment

Petitioner reported that her symptoms improved over the course of her IVIG treatment, and she was discharged on September 6, 2015. *Id.* at *4. Her discharge note included a "'concern[] for a possible recurrence of GBS.'" *Id.* (quoting ECF No. 7-7 at 369–70). At a follow-up appointment on October 13, 2015, Dr. Smith evaluated Petitioner for chronic inflammatory demyelinating polyradiculoneuropathy ("CIDP") and took note of her medical history, including recurrent GBS versus CIDP, viral infections, flulike symptoms, diarrhea, weakness, and Tdap vaccinations. *Id.* At this particular evaluation, Petitioner presented with "nystagmus, abnormal facial expression and weakness, decreased hearing to finger rub, decreased reflexes, and decreased sensation to light touch in all extremities." *Id.* Dr. Smith specifically noted that Petitioner experienced worsening CIDP, "slightly worsened proximal weakness," and suppressed reflexes in the upper extremities. *Id.* As a result, Dr. Smith prescribed IVIG two days per month and suggested that Petitioner return to physical therapy. *Id.*

Over the next few weeks, Petitioner attended several physical therapy sessions at Kindred Rehabilitation Hospital before she "discharged herself due to the long drive to therapy" on November 17, 2015. *Id.* On December 10, 2015, Petitioner met with Dr. Smith for bilateral hearing loss, CIPD, and mild memory loss. *Id.* She underwent IVIG treatment at the time and reported that her limb endurance had improved, and her previous facial sensory dysesthesias had resolved. *Id*. However, her posture and balance problems continued. *Id*. Dr. Smith suggested a neuropsychology referral due to Petitioner's baseline deficits from her "previous postvaccination event . . . ." *Id*. Dr. Smith also discussed the following with Petitioner: vestibular rehabilitation, when GBS is actually CIDP, when therapy for a chronic problem can help repair in a recurrent but inactive process, and central nervous system involvement in a post-vaccination central and peripheral nervous system injury. *Id*. Dr. Smith referred Petitioner to physical and occupational therapy and ordered an EMG/NCS. *Id.*

Several months later, on March 16, 2016, Petitioner saw Dr. Smith for a follow-up appointment regarding her recurrent GBS. *Id*. Petitioner was not receiving IVIG treatment at the time and, while she was clinically stable, she was experiencing issues with limb posture and endurance. *Id*. Petitioner also had "ongoing weakness in multiple muscles . . . in both the upper and lower extremities." *Id*. Dr. Smith diagnosed Petitioner with "GBS, bilateral hearing loss (due to [the] initial episode of GBS), and mild memory disturbance from 'post episode of post-vaccination GBS+ . . . with balance and memory changes similar to those from [the] previous episode 10 years earlier.'" *Id*. (quoting ECF No. 7-9 at 34). On April 6, 2016, Petitioner's repeat EMG/NCS "showed evidence of a 'diffuse polyradiculopathy with previous denervation and incomplete reinnervation.'" *Id*. at *5 (quoting ECF No. 28-1 at 7-9.).

In December 2016, "Petitioner's most recent EMG 'documented no new active lesions (not ongoing CIDP), but still showed evidence of distal demyelination residual yet to recover

from her most recent episode of weakness.'" *Id*. (quoting ECF No. 7-9 at 3, 17). In addition, Petitioner was still experiencing continuing deficits in "fatigue, endurance, and focus, with milder deficits in weakness and sensory function." *Id*. At a follow-up visit on May 25, 2018, Dr. Smith noted that, while Petitioner was slowly improving in strength and endurance, she still experienced ongoing weakness of the extremities, decreased to absent reflexes, and weakness of the facial muscles. *Id*. As a result, Dr. Smith's diagnosis was once again GBS, "though Petitioner '[i]nitially [had] some features suggestive of CIDP . . .' with lower facial weakness due to recurrent GBS, and bilateral hearing loss after her initial episode of GBS." *Id*. (quoting ECF No. 7-9 at 30). Petitioner's last visit with Dr. Smith in the record was on March 13, 2019. *Id.* (citing ECF No. 17-2 at 18).

B. Expert Reports

The Court will summarize the reports of the parties' expert witnesses, which the Chief Special Master's decision recounted more comprehensively. *See* Entitlement Decision at *5–11.

1. Petitioner's First Expert Report (Carlo Tornatore, M.D.)

Dr. Tornatore, a board-certified neurologist, a Professor and Chairman of the Department of Neurology at Georgetown University Medical Center, and Chairman and Neurologist-in-Chief of the Department of Neurology at Medstar Georgetown University Hospital in Washington, D.C., completed two written reports for Petitioner supporting her assertion that the Tdap vaccine can cause GBS and that it did so in this case. *Id.* at *5 (citing ECF Nos. 38-1 & 43-1). First, "Dr. Tornatore opined that Petitioner has GBS, which he defined as an autoimmune demyelinating neuropathy of the peripheral nervous system." *Id*. at *6. Dr. Tornatore contended that "foreign antigens (e.g., viral or bacterial infection or vaccination) result in activation of the immune system—a normal mechanism to clear the offending antigen. . . . However, in rare cases, the activation is misdirected, and both the humoral and cellular arms of the immune system (the innate and adaptive responses, respectively) attack components of its own nervous system." *Id.* (citation omitted).

In regard to GBS specifically, Dr. Tornatore asserted that "the target of the immune response is the myelin (and in some cases the axons) of the peripheral nervous system," and "[t]he resulting injury is manifested clinically by numbness and weakness of the extremities, truncal muscles and muscles of the face and neck." *Id*. Thus, according to Dr. Tornatore, unilateral and bilateral facial weakness, like that experienced by Petitioner, is a common symptom of GBS. *Id*. Based on Petitioner's two episodes of GBS, her first beginning on August 21, 2005, and her second on September 1, 2015, Dr. Tornatore characterized Petitioner's diagnosis as "recurrent GBS." *Id*. According to Dr. Tornatore, Petitioner's symptoms and test results after both episodes—including facial diplegia, motor weakness, early acute proximal demyelination, normal cerebrospinal fluid protein levels, and nadir within four weeks of onset—are consistent with early GBS. *Id*.

Next, Dr. Tornatore contended that the Tdap vaccine can theoretically cause GBS. *Id*. He asserted that the pathogenesis of GBS "is affected by molecular mimicry post-exposure to viral or bacterial antigens (which in turn resemble or mimic, host structures—meaning antibodies

to the foreign antigens mistakenly attack the self)." *Id*. Dr. Tornatore cited several sources[2] to support his assertion that GBS can be associated with the Tdap vaccine and concluded "that the Tdap vaccine more likely than not could result in autoimmune peripheral nerve demyelination clinically presenting as GBS." *Id*. Moreover, Dr. Tornatore indicated that Petitioner's medical history was consistent with his causation theory because other than the Tdap vaccine, Petitioner had no other prior events that could have caused the GBS. *Id*. at *7. Dr. Tornatore also pointed to the fact that, in Petitioner's medical records, her most recent doctor, Dr. Smith, implied the possibility of Tdap-induced GBS. *Id*.

In conclusion, Dr. Tornatore opined that the prompt timeframe for Petitioner's symptoms' onset (within forty-eight hours of receiving the Tdap vaccination) was medically acceptable. *Id.* This is because a quick response to a second antigenic challenge was reasonable within a twenty-four hour period when a patient's immune system was previously primed by an earlier exposure to the Tdap vaccine, as Petitioner's was here. *Id*. Dr. Tornatore cited several pieces of literature to support his assertion, including literature discussing "the acceleration of the immune response after previous exposure . . . ." *Id*. (citing Lawrence B. Schonberger et al., *Guillain-Barré Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976–1977*, 110 AM. J. EPIDEMIOLOGY 105, 120–22 (1979), filed as ECF No. 47-4).

2. Respondent's Expert Report (Timothy Vartanian, M.D., Ph.D.)

Dr. Vartanian, a board-certified neurologist, who is a professor at Weill Cornell Medical College and an attending neurologist at New York Presbyterian Hospital, completed a written report for Respondent supporting the contention that there was no causal relationship between Petitioner's Tdap vaccine and her GBS symptoms. *Id*. at *8. In his report, Dr. Vartanian first acknowledged that Petitioner's symptoms in 2005 (acellularity, elevated protein levels, enhancement of the seventh and eighth nerve complex, and uncommon facial symptoms) were consistent with GBS. *Id.* Dr. Vartanian also agreed that Petitioner's 2015 episode showed symptoms often associated with GBS. *Id.* However, Dr. Vartanian opined that further testing and Petitioner's medical record did not establish an evolution of symptoms that suggested new autoimmune or inflammatory demyelination and, therefore, did not support the conclusion that Petitioner experienced a recurrence of GBS in 2015. *Id.* Dr. Vartanian did not offer an alternative diagnosis in his report. *Id.*

[2] Dr. Tornatore cited the following in this report: Schonberger et al., *supra*, at 120–22. N. Souayah et al*., Guillain-Barre Syndrome After Vaccination in United States: A Report from the CDC/FDA Vaccine Adverse Event Reporting System* (1990–2005), 11 NEUROMUSCULAR DISEASE 1, 5 (2009), filed as Ex. 45 (ECF No. 47-7) ("[o]ur results suggest that vaccines other than influenza vaccine can be associated with GBS."). F. E. Shaw et al., *Postmarketing Surveillance for Neurologic Adverse Events Reported After Hepatitis B Vaccination*, 127 AM. J. EPIDEMIOLOGY 337, 344–50 (1988), filed as Ex. 44 (ECF No. 47-6); M. Khamaisi et al., *Guillain-Barré Syndrome Following Hepatitis B Vaccination*, 22 CLINICAL & EXPERIMENTAL RHEUMATOLOGY 767, 768–69 (2004), filed as Ex. 51 (ECF No. 57-2). ECF No. 38-1 ("Tornatore First Report") 22–24.

Furthermore, Dr. Vartanian maintained that reliable medical literature[3] did not support Dr. Tornatore's contention that the Tdap vaccine could cause an autoimmune process mediated by molecular mimicry and lead to GBS. *Id.* at *9. Dr. Vartanian went on to opine that Petitioner's medical history was inconsistent with the explanation that the Tdap vaccine caused her injury. *Id.* at *10. First, Dr. Vartanian noted that the cause of Petitioner's 2005 bout of GBS was incorrectly attributed to a Tdap vaccination that the record does not confirm as having actually occurred, and the notes in Petitioner's medical record also acknowledged the possibility of multiple other antecedent infections that could have been the cause of Petitioner's GBS. *Id.*; *see also* ECF No. 41 ("Vartanian Report") at 11. Second, with regard to Petitioner's 2015 GBS incident, Dr. Vartanian indicated that Petitioner once again showed symptoms of other antecedent infections (an abscess on her foot from a nail, fever, and nausea) that could have been the cause of her GBS, especially since, according to Dr. Vartanian, "antecedent gastrointestinal or respiratory infections are by far most closely associated with GBS, whereas the Tdap vaccine has only anecdotal associations." Vartanian Report at 11; Entitlement Decision at *10. Finally, Dr. Vartanian opined that Petitioner's onset, one and a half days after her Tdap vaccination, was not enough time for humoral or cellular immunity to cause an injury to the nervous system because, while the memory cells can respond quickly when confronting the same previously-encountered pathogen (or vaccine), in most cases, it still takes about four days for a memory response to result in an effective immune reaction. Entitlement Decision at *10; Vartanian Report at 16.

3. Petitioner's Second Expert Report (Carlo Tornatore, M.D.)

Dr. Tornatore wrote a second report in response to Dr. Vartanian's report. *See* ECF No. 43-1 ("Tornatore Second Report"); Entitlement Decision at *7. In that report, Dr. Tornatore maintains that GBS was Petitioner's proper diagnosis in 2015 because: (1) Petitioner's September 2, 2015, electromyography ("EMG") results showed signs of an acute inflammatory

[3] Dr. Vartanian cited the following in his report: W. Yih et al., *An Assessment of the Safety of Adolescent and Adult Tetanus–Diphtheria–Acellular Pertussis (Tdap) Vaccine, Using Active Surveillance for Adverse Events in the Vaccine Safety Datalink*, 27 VACCINE 4257, 4261 (2009), filed as Ex. A, Tab 18 (ECF No. 42-18) ("[w]e found no evidence of an association between Tdap and any of the five predefined adverse events [including GBS] in a surveillance period that included 660,245 doses of Tdap over the course of 145 weeks"); J. Nelson et al., *Adapting Group Sequential Methods to Observational Postlicensure Vaccine Safety Surveillance: Results of a Pentavalent Combination Dtap-IPV-Hib Vaccine Safety Study*, 177 AM. J. EPIDEMIOLOGY 131, 131 (2013), filed as Ex. A, Tab 13 (ECF No. 42-13) ("[n]o increased risk was detected among 149,337 DTaP-IPV-Hib vaccinees versus historical comparators for any outcome, including . . . Guillain-Barré syndrome . . . ."); J. Tuttle et al., *The Risk of Guillain-Barre Syndrome After Tetanus-Toxoid-Containing Vaccines in Adults And Children in The United States*, 87 AM. J. PUB. HEALTH 2045, 2045–47 (1997), filed as Ex. D (ECF No. 58-1) (concluding that if an association exists, it must be extremely rare and not of public health significance); M. Daley et al., *Safety of Diphtheria, Tetanus, Acellular Pertussis and Inactivated Poliovirus (Dtap–IPV) Vaccine*, 32 VACCINE 3019, 3019 (2014), filed as Ex. A, Tab 6 (ECF No. 42-6) ([T]here was no evidence of increased risk for any of the pre-specified adverse events monitored."); R. Baxter et al., *Lack of Association of Guillain-Barre Syndrome with Vaccinations*, 57 CLINICAL INFECTION DISEASES 197, 197 (2013), filed as Ex. A, Tab 1 (ECF No. 42-1) (finding no evidence of an increased risk of GBS following vaccinations of any kind). Vartanian Report at 14–16.

process of the proximal nerve roots; (2) following her EMG report, Petitioner was immediately treated with IVIG, the typical treatment for GBS; and (3) Petitioner's follow-up EMG showed signs of improvement, indicating the effectiveness of the immunotherapy treatment and the monophasic course of her illness, thus indicating to Dr. Tornatore that Petitioner had GBS. Tornatore Second Report at 27; Entitlement Decision at *7.

In response to Dr. Vartanian's assertion regarding molecular mimicry, Dr. Tornatore maintained that Dr. Vartanian did not dispute the scientific mechanisms of molecular mimicry in his report. Entitlement Decision at *7. Dr. Tornatore went on to suggest that while Dr. Vartanian contended there was a lack of epidemiologic data to support a causal relationship between GBS and the Tdap vaccine, Dr. Tornatore opined that epidemiology cannot rule out rare events such as vaccine injuries. *Id.* Finally, Dr. Tornatore also disagreed with Dr. Vartanian's opinion regarding Petitioner's onset and argued that the immune response could possibly result in a neurologic injury within 48 hours of vaccination because, immediately after exposure to a foreign antigen, there is a measurable increase in the immune response, making Petitioner's one-and-a-half-day onset medically acceptable. *Id.* at *8.

C. Procedural History

On August 28, 2018, Petitioner filed a petition for compensation under the Vaccine Act, alleging that she suffered a recurrent episode of GBS as a result of the Tdap vaccine she received on August 30, 2015. ECF No. 1. Expert reports were filed through January 2022. Entitlement Decision at *10. On January 11, 2022, the Chief Special Master issued an Order determining that the claim could be decided by a ruling on the record. *Id.* Petitioner filed her motion and accompanying exhibits in support of a ruling on the record on April 22, 2022. ECF No. 46. Respondent filed a response on July 7, 2022, ECF No. 53, and Petitioner filed a reply on August 1, 2022, ECF No. 55. The Chief Special Master issued a ruling on the record denying entitlement on March 23, 2023, determining that "Petitioner ha[d] not preponderantly established that the Tdap vaccine [s]he received could cause GBS, or that it did so to her in a medically-acceptable timeframe." Entitlement Decision at *1. Petitioner timely filed a motion for review on April 24, 2023, setting forth the following objections:

1. The [Chief] Special Master improperly elevated Petitioner's burden of proof under *Althen* prong one by requiring direct medical proof of the mechanism of injury and by overlooking evidence of petitioner's pre-existing aberrant immune system.

2. The Chief Special Master's analysis of *Althen* prongs two and three were similarly infected by the Chief Special Master's imposition of a heightened standard regarding the evidence he would accept for Petitioner to prove that she actually received a Tdap vaccine prior to the onset of her GBS in 2005.

ECF No. 61. Respondent filed a response on May 24, 2023, ECF No. 64, and the Court held oral argument on July 27, 2023.

DISCUSSION

A. Standard of Review

Under the Vaccine Act, this Court has jurisdiction to review the entitlement decisions of special masters. *See* 42 U.S.C. § 300aa–12(e)(1). In reviewing a special master's decision, the Court may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
>
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa–12(e)(2). In other words, "[u]nder the Vaccine Act, the Court of Federal Claims reviews [a special master's] decision to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.'" *Markovich v. Sec'y of Health & Hum. Servs.*, 477 F.3d 1353, 1355–56 (Fed. Cir. 2007), *cert. denied*, 552 U.S. 816 (2007) (citing 42 U.S.C. § 300aa–12(e)(2)(B)).

With regard to factual determinations, the Court does not "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." *Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011). If the "special master's factual findings are 'based on evidence in the record that [is] not wholly implausible, the Court cannot find that a special master was arbitrary and capricious.'" *Id.* (quoting *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1363 (Fed. Cir. 2000)). In other words, "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines on Behalf of Sevier v. Sec'y of Dep't of Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991); *see also Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed Cir. 1993) ("[O]n review, the Court of Federal Claims is not to second guess [a s]pecial [m]aster[']s fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process."); *Munn v. Sec'y of Health & Hum. Servs.*, 970 F.2d 863, 870 (Fed. Cir. 1992) (arbitrary and capricious standard applied to "both fact-findings and fact-based conclusions . . . is a standard well understood to be the most deferential possible"). In short, the Court affords a special master a great deal of deference with regard to factual conclusions and how the evidence is weighed, and, as a result, a petitioner faces a heavy burden to overturn a special master's factual and evidentiary determinations.

As it relates to questions of law, under the "not in accordance with law" standard, the Court may review *de novo* a special master's decision with regard to statutory or other purely

legal issues. *H.L. v. Sec'y of Health & Hum. Servs.*, 129 Fed. Cl. 165, 169 (2016); *accord Hines*, 940 F.2d at 1527 ("The 'not in accordance with the law' aspect of the standard of review is . . . involved [in cases in which there is a] dispute over statutory construction or other legal issues."). Finally, the Court may review a special master's discretionary rulings for "abuse of discretion." *Munn*, 970 F.2d at 870 n.10.[4]

B. Petitioner's Legal Standard Under the Vaccine Act

Under the Vaccine Act, a petitioner may seek compensation for two different types of vaccine injuries. First, a petitioner is entitled to compensation "when an injury or condition listed in the Vaccine Injury Table . . . begins to manifest itself within the time specified in the Table for the vaccine in question." *Hines*, 940 F.2d at 1524 (citing 42 U.S.C. §§ 300aa–11(c)(1)(C)(i), 300aa–14(a)). In these so-called "table injury cases," causation is presumed. *Id.* Second, "for injuries not listed in the Table, or which do not occur within the time period stipulated in the Table, the Vaccine Act authorizes recovery only if the petitioner proves actual causation." *Id.* at 1524–25 (citing 42 U.S.C. § 300aa–11(c)(1)(C)(ii)). A petitioner bears the burden of establishing actual causation in a non-table case by a preponderance of the evidence. *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010). If a petitioner satisfies his or her burden, then the burden shifts to the Secretary to prove "[by] a preponderance of the evidence that [the petitioner's injury] is due to factors unrelated to the administration of the vaccine described in the petition." *See* 42 U.S.C. § 300aa–13(a)(1)(B); *accord Walther v. Sec'y of Health & Hum. Servs.*, 485 F.3d 1146, 1150 (Fed. Cir. 2007). Indeed, if a petitioner makes out a prima facie case, he or she "bears no burden to rule out possible alternative causes." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008) (citing *Walther*, 485 F.3d at 1149–50).

Here, Petitioner's asserted injury—GBS allegedly caused by the Tdap vaccine—is a "non-table" injury. Entitlement Decision at *11; 42 C.F.R. § 300.3(a). To prove actual causation by a preponderance of the evidence in a non-table case, a petitioner must demonstrate the following:

> (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

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[4] "An abuse of discretion may be found when (1) the court's decision is clearly unreasonable, arbitrary, or fanciful; (2) the decision is based on an erroneous conclusion of the law; (3) the court's findings are clearly erroneous; or (4) the record contains no evidence upon which the court rationally could have based its decision." *Simmons v. Sec'y of Health & Hum. Servs.*, 875 F.3d 632, 635 (Fed. Cir. 2017) (citing *Hendler v. United States*, 952 F.2d 1364, 1380 (Fed. Cir. 1991)). However, the abuse of discretion is not frequently applied in vaccine appeals. *See Munn*, 970 F.2d at 870 n.10 (abuse of discretion standard "will rarely come into play except where the special master excludes evidence"); *Caves v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 119, 131 (2011) (abuse of discretion is "applicable when the special master excludes evidence or otherwise limits the record upon which he relies"). Here, the Chief Special Master did not exclude evidence or limit the record in any way; therefore, the abuse of discretion standard is not applicable.

Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed Cir. 2005).

To meet prong one, "a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" *Broekelschen*, 618 F.3d at 1345 (quoting *Knudsen v. Sec'y of Health & Hum. Servs.,* 35 F.3d 543, 548–49 (Fed. Cir. 1994)). A petitioner need not establish a plausible medical theory with conclusive evidence. *See Solak v. Sec'y of Health & Hum. Servs.*, No. 14–869 V, 2020 WL 9173158, at *19 (Fed. Cl. Spec. Mstr. Feb. 19, 2020) ("A petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstrations of a specific mechanism, or a generally accepted medical theory."). Nonetheless, a theory "that lacks any empirical support will have limited persuasive force." *Caves v. Sec'y of Dep't of Health & Hum. Servs.*, 100 Fed. Cl. 119, 134 (2011), *aff'd sub nom. Caves v. Sec'y of Health & Hum. Servs.*, 463 F. App'x 932 (Fed. Cir. 2012).

To satisfy prong two, a petitioner "must show that the vaccine was the 'but for' cause of the harm," *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1356 (Fed. Cir. 2006), often by using facts and medical opinions derived from the petitioner's medical records, *Althen*, 418 F.3d at 1278. However, while medical records and statements of treating physicians should be evaluated and weighed carefully, they are not binding on a special master or this Court. *See* 42 U.S.C. § 300aa–13(b)(1)(B) ("Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court."); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("[T]here is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted.").

The third *Althen* prong requires a petitioner to prove a "medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury." 418 F.3d at 1281. Specifically, a petitioner needs to submit "proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan*, 539 F.3d at 1352. The third prong closely links with the first prong because the acceptable timeframe must coincide with a petitioner's theory of how a particular vaccine can cause the injury. *Id.* In reality, the third *Althen* prong can be broken down into two steps: (1) "establish the timeframe for which it is medically acceptable to infer causation, that is, the timeframe in which symptoms would be expected to arise if the [disorder] was caused by the vaccination"; and (2) "show that the onset of the [disorder] occurred during this causation period." *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011).

C. *Althen* Prong One As Applied to Petitioner's Claim

As stated above, the Chief Special Master determined that Petitioner failed to meet the required burden of proof for all three *Althen* prongs. Accordingly, in order to successfully challenge the Chief Special Master's determination, Petitioner must demonstrate that the Chief Special Master's decision was arbitrary, capricious, or otherwise not in accordance with law with regard to all three prongs of the *Althen* test. *See* 42 U.S.C. § 300aa–12(e)(2)(B). Because the

Court determines that Petitioner fails to demonstrate that the Chief Special Master's determination with regard to *Althen* prong one was in error, the Court must deny her motion for review.[5]

Under *Althen* prong one, Petitioner must provide a "medical theory causally connecting the vaccination [Tdap] and the injury [GBS]." 418 F.3d at 1278. Such a theory must be "legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 549. Petitioner need not resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu ex rel. Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1325–26 (Fed. Cir. 2006)). However, "[a] petitioner must provide a 'reputable medical or scientific explanation' for [his or her] theory [, and thus] [w]hile it does not require medical or scientific certainty, it must still be 'sound and reliable.'" *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351 (Fed. Cir. 2019) (quoting *Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010) and *Knudsen*, 35 F.3d at 548–49).

Here, Petitioner attempts to satisfy *Althen's* first prong with the medical theory that the Tdap vaccine could cause GBS via molecular mimicry, a concept that is well-established in immunology. *See Pierson v. Sec'y of Health & Hum. Servs.*, No. 17–1136 V, 2022 WL 322836, at *23 (Fed. Cl. Spec. Mstr. Jan. 19, 2022) ("Molecular mimicry is a well-established theory in the Vaccine Program and has been persuasively linked to several autoimmune conditions.") (collecting cases). Despite the fact that molecular mimicry itself is a well-established concept, the Chief Special Master found that Petitioner failed to establish "that the Tdap vaccine could cause GBS with sufficient reliable scientific or medical evidence." Entitlement Decision at *19. According to the Chief Special Master, "more must be done to preponderantly establish causation than simply rais[ing] the flag of molecular mimicry as a generally-reliable concept." *Id.* "Instead, claimants and their experts must provide sufficient connective evidence to allow a conclusion that it is more likely than not the specific vaccine in question that could cause the relevant injury." *Id*. (internal quotations omitted).

In her motion for review, Petitioner argues that the Chief Special Master "improperly elevated petitioner's burden of proof under *Althen* prong one" by requiring "direct proof of molecular mimicry as the mechanism" of injury. ECF No. 62 at 7, 12. She posits that the Chief Special Master did so by failing to adequately address (1) the Schonberger article cited by Petitioner's expert, Dr. Tornatore, that discusses an association between GBS and the swine flu and tetanus vaccines, and (2) the cases in which other special masters have found that the Tdap vaccine can cause GBS. *See id.* at 11–12. Petitioner further argues that the Chief Special Master did not address Petitioner's recurrence of GBS and, in doing so, "entirely failed to ask the right question." *Id.* at 13–14. This, according to Petitioner, heightened her burden of proof for *Althen* prong one. Moreover, Petitioner asserts that the cases and medical literature cited by both the Chief Special Master and Respondent's expert, Dr. Vartanian, "which did not observe an association between the Tdap vaccine and injury," did not discuss "individuals who suffered multiple episodes of GBS," like Petitioner, and thus were given more weight than they deserved. *See id.* at 13–15. Accordingly, Petitioner asserts that the "[Chief Special Master's] approach

[5] Given this finding regarding prong one, the Court need not address Plaintiff's arguments regarding prongs two and three of the *Althen* test.

[was] contrary to Program precedent from the Federal Circuit and the underlying purpose of the Vaccine Act." *Id.* at 12.

Although Petitioner raises several issues with the Chief Special Master's determination regarding *Althen* prong one, the Court need not address much of Petitioner's argument as the Court must concur with the Chief Special Master that Petitioner simply failed to show the necessary causal relationship between the Tdap vaccine and GBS. While Petitioner and Dr. Tornatore put forth the well-established medical theory of molecular mimicry as the mechanism through which the Tdap vaccine could cause GBS, nowhere in Dr. Tornatore's expert reports, nor in Petitioner's briefs, do they specifically tie the Tdap vaccine to GBS through molecular mimicry.

For example, Dr. Tornatore explains that during the process of molecular mimicry, if a viral or bacterial antigen in a vaccine shares homology with host antigens, the vaccine's immune response will be "directed at both the injected antigens and host antigens," resulting in autoimmunity. Tornatore First Report at 23. Dr. Tornatore goes on to suggest the possibility that "the pathogenesis of GBS is due to molecular mimicry post-exposure to viral or bacterial antigens." *Id.* at 22. However, Dr. Tornatore never actually explains how molecular mimicry might occur from the Tdap vaccine specifically, nor does he elaborate on how molecular mimicry could cause the specific autoimmune system reaction that could cause GBS. To quote the Chief Special Master, Dr. Tornatore

> did not attempt to establish the kind of homology between vaccine antigens and self structures in the nerves that is a common starting point for molecular mimicry when offered as a mechanistic explanation. He also pointed to no specific antibody created in response to the Tdap vaccine that might cross-react against nerve myelin in the manner GBS is believed to progress.

Entitlement Decision at *19. Instead, Dr. Tornatore's expert opinion deals in generalities and uses the well-established concept of molecular mimicry to offer a generally accepted, but unspecified, theory that a vaccine can result in molecular mimicry, which can then cause an autoimmune reaction resulting in injury. In fact, because Dr. Tornatore does not offer any specific explanation as to the distinct connection between Tdap, molecular mimicry, and GBS, one could take Dr. Tornatore's causation theory and substitute any table vaccine (*e.g.*, the measles vaccine) and any autoimmune disorder (*e.g.*, autoimmune encephalitis) and Dr. Tornatore's expert report's discussion of molecular mimicry would require absolutely no changes. That is how general his molecular mimicry theory is—it does not matter which vaccine and which autoimmune disorder are plugged in. But *Althen* prong one requires more.

There is nothing in Dr. Tornatore's report that explains or even alludes to what antigens or structures in the Tdap vaccine could share homology with possible host antigens and how these antigens could react in the manner GBS is believed to progress. Additionally, the GBS literature that Dr. Tornatore cites to in support of his causation theory speaks only to a causal relationship between GBS and the tetanus and swine flu vaccines. *See* Tornatore First Report at 22–24. The literature upon which he relies make no mention of any causal connection between GBS and the Tdap vaccine. *See id.* Dr. Vartanian, on the other hand, cited literature that

specifically found no evidence of an association between the Tdap vaccine and GBS.[6] Vartanian Report at 14–16. Finally, and unfortunately for Petitioner, she offers no other evidence—outside of Dr. Tornatore's report—to support her *Althen* prong one argument that the Tdap vaccine could cause GBS via molecular mimicry.

As a result, the Court must uphold the Chief Special Master's determination that Petitioner did not meet her burden under the first *Althen* prong. Although Petitioner argues that the Chief Special Master "increase[d] the burden placed on [P]etitioner[] in offering a scientific theory linking vaccine to injury" and "improperly required petitioner to prove the specific biologic mechanism as to how Tdap vaccine generally can cause GBS," ECF No. 62 at 9, 14, neither the Chief Special Master, nor the Court, is asking Petitioner to *prove* anything. Rather, Petitioner (and Petitioner's expert) simply failed to explain *how* the specific vaccine at issue (Tdap) *could possibly cause* the experienced autoimmunity (GBS). Neither Dr. Tornatore, nor Petitioner, answered the question that must be addressed to satisfy the first *Althen* prong: what reputable medical theory causally connects the received vaccination (Tdap) and the experienced injury (GBS)? Instead, they simply offered the reliable and generally-accepted medical theory of molecular mimicry but never explained how that theory could form a causal connection specifically between the Tdap vaccine and GBS. And while Petitioner need not identify or prove that the Tdap vaccine actually caused GBS via molecular mimicry, *Knudsen*, 35 F.3d at 549, simply citing "molecular mimicry" as the causation theory does not meet the *Althen* prong one burden without additional evidence that offers some actual connection between molecular mimicry, Tdap, and GBS. *See, e.g.*, *McKown v. Sec'y of Health & Hum. Servs.*, No. 15-1451 V, 2019 WL 4072113, at *50 (Fed. Cl. Spec. Mstr. July 15, 2019) (citing *Devonshire v. Sec'y of the Dep't of Health & Hum. Servs.*, No. 99-031 V, 2006 WL 2970418, at *15 (Fed. Cl. Spec. Mstr. Sept. 28, 2006), *aff'd sub nom. Devonshire v. Sec'y of Dep't of Health & Hum. Servs.*, 76 Fed. Cl. 452 (2007)).

In addition, Petitioner also argues that the Chief Special Master heightened the *Althen* prong one standard by failing to address the fact that Petitioner suffered a recurrence of GBS, which, Petitioner asserts, "formed the entire basis of Dr. Tornatore's two expert reports." ECF No. 62 at 14. Petitioner goes on to make a "challenge-rechallenge" argument, *i.e.*, the idea that she was exposed to the Tdap vaccine, reacted in a certain way, was given the same vaccine again, and reacted to it in a similar way as before. *See id.* at 14–15; *Nussman v. Sec'y of Health & Hum. Servs.*, No. 99–500–V, 2008 WL 449656, at *9 (Fed. Cl. Spec. Mstr. Jan. 31, 2008), *aff'd,* 83 Fed. Cl. 111 (2008). Petitioner's argument fails for two reasons. First, Petitioner discusses this argument in relation to *Althen* prong one, but challenge-rechallenge arguments relate to the second *Althen* prong. *Nussman*, 2008 WL 449656, at *12 n.6 ("The challenge-rechallenge model is not a medical theory. The challenge-rechallenge paradigm is a method, based in logic, that can assist in proving that a vaccine caused an injury. As such, challenge-rechallenge is discussed in the second prong of *Althen.* The underlying logic can be used in a

[6] Petitioner argues that the Chief Special Master incorrectly rejected Dr. Tornatore's theory "in favor of Dr. Vartanian's citation to several pieces of medical literature 'which did not observe an association between the Tdap vaccine and injury.'" ECF No. 62 at 13 (citing Entitlement Decision at *19). The Court need not address this so-called battle of the experts argument because, as mentioned above, Petitioner's expert never actually addresses the real question contemplated by *Althen* prong one: how could the Tdap vaccine itself cause GBS specifically via molecular mimicry?

variety of disciplines, not just medicine."). Thus, it is irrelevant whether the Chief Special Master correctly addressed Petitioner's recurrent GBS in his discussion of the first *Althen* prong. Second, as discussed above, even if a challenge-rechallenge argument was relevant to an *Althen* prong one analysis, Petitioner still fails to establish how recurrent GBS could possibly be causally connected to the Tdap vaccine via molecular mimicry or any other reputable medical theory.

Finally, Petitioner addresses, and the Chief Special Master concedes, the fact that other special masters have found that the Tdap vaccine can cause GBS. *See*, *e.g.*, *Mohamad v. Sec'y of Health & Hum. Servs.*, No. 16–1075 V, 2022 WL 711604, at *18 (Fed. Cl. Spec. Mstr. Jan. 27, 2022); *see also Swaiss v. Sec'y of Health & Hum. Servs.*, No. 15–286 V, 2019 WL 6520791, at *23–27 (Fed. Cl. Spec. Mstr. Nov. 4, 2019); *Harris v. Sec'y of Health & Hum. Servs.*, No. 18–944 V, slip op. (Fed. Cl. Spec. Mstr. Feb. 21, 2023). However, as both Respondent and the Chief Special Master point out, there are also cases in which special masters have found that petitioners have failed to show reliable scientific evidence of an association between the Tdap vaccine and GBS. *See, e.g.*, *Tompkins v. Sec'y of Health & Hum. Servs.,* No. 10–261 V, 2013 WL 3498652 (Fed. Cl. Spec. Mstr. June 21, 2013), *mot. for review den'd*, 117 Fed. Cl. 713 (2014); *Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601 V, 2012 WL 3609993 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x 999 (Fed. Cir. 2013). These sets of cases differ from one another in several critical ways.

First, in *Mohamad*, the petitioner won on *Althen* prong one because respondent had publicly accepted the proposition that a DTap vaccine can cause GBS. *See generally Mohamad*, 2022 WL 711604, at *9–18. Second, in *Swaiss*, the special master acknowledged "that there [were] not significant verified case reports, population studies, and animal experiments supporting an association between Tdap vaccine and the most common GBS variants . . . ." 2019 WL 6520791, at *27. However, he found that the petitioner still met *Althen* prong one because the "case involve[d] a GBS variant involving selective damage of the small fibers" that are difficult to obtain objective evidence of and are thus "likely to be overlooked," resulting in limited case reports on the matter. *Id.* Therefore, the special master found that "[p]etitioner should not be faulted for the lack of published literature on point with his case." *Id.* Finally, in *Harris*, Petitioner's *Althen* prong one argument relied on other reputable medical theories other than molecular mimicry alone. *See generally* No. 18–944 V, slip op.

In contrast, but similar to the case at hand, the special master in *Isaac*, another case in which Dr. Tornatore served as an expert, found that the petitioner did not provide a causal connection between the Tdap vaccine and GBS because while "Dr. Tornatore explained how molecular mimicry might cause GBS" and "described the process of molecular mimicry . . . he did not link tetanus or Td vaccination to GBS by the process of molecular mimicry." *See* 2012 WL 3609993, at *21. The same thing occurred here: Dr. Tornatore suggested that molecular mimicry could cause GBS, he explained generally how molecular mimicry occurs, but he failed to identify how the Tdap vaccine itself could result in molecular mimicry in a way that could then go on to cause GBS specifically. As a result, the Court finds that, no matter what standard the Chief Special Master applied in his *Althen* prong one analysis, he was correct to the extent that Petitioner failed to provide an adequate medical theory casually connecting Petitioner's injury to the vaccine she received.

CONCLUSION

For the foregoing reasons, the Court finds that Petitioner has failed to establish that the Chief Special Master's Entitlement Decision with regard to *Althen* prong one was arbitrary, capricious, or otherwise not in accordance with law. Accordingly, Petitioners' Motion for Review is **DENIED,** and the decision of the Chief Special Master is **SUSTAINED**. The Clerk of the Court shall enter judgment accordingly.

IT IS SO ORDERED.

s/ Zachary N. Somers
ZACHARY N. SOMERS
Judge